



## EU DECLARATION OF CONFORMITY

**Manufacturer:** Toruńskie Zakłady Materiałów Opatrunkowych S.A. (TZMO SA)

**Manufacturer address:** ul. Żółkiewskiego 20/26, Toruń, 87-100, Poland

**SRN number:** PL-MF-000002200

Product name	Types/models	Version	BASIC UDI-DI code
BOM Flat paper-film pouches for sterilisation	with and without indicators of sterilisation; 48mm x 98mm; 50mm x 92mm; 50mm x 140mm; 50mm x 150mm; 50mm x 200mm; 50mm x 201mm; 50mm x 240mm; 50mm x 250mm; 50mm x 280mm; 50mm x 800mm; 50mm x 830mm; 50mm x 900mm; 60mm x 135mm; 60mm x 150mm; 62mm x 140mm; 65mm x 130mm; 72mm x 148mm; 75mm x 110mm; 75mm x 150mm; 75mm x 160mm; 75mm x 200mm; 75mm x 210mm; 75mm x 250mm; 75mm x 270mm; 75mm x 300mm; 75mm x 350mm; 75mm x 440mm; 75mm x 450mm; 75mm x 600mm; 75mm x 700mm; 75mm x 750mm; 75mm x 800mm; 75mm x 900mm; 75mm x 910mm; 80mm x 180mm; 100mm x 150mm; 100mm x 200mm; 100mm x 230mm; 100mm x 240mm; 100mm x 250mm; 100mm x 270mm; 100mm x 300mm; 100mm x 350mm; 100mm x 400mm; 100mm x 420mm; 100mm x 460mm; 100mm x 550mm; 100mm x 560mm; 100mm x 570mm; 100mm x 600mm; 100mm x 700mm; 100mm x 850mm; 120mm x 150mm; 120mm x 170mm; 120mm x 200mm; 120mm x 250mm; 120mm x 300mm; 120mm x 320mm; 120mm x 350mm; 120mm x 400mm; 150mm x 200mm; 150mm x 230mm; 150mm x 235mm; 150mm x 240mm; 150mm x 250mm; 150mm x 270mm; 150mm x 280mm; 150mm x 300mm; 150mm x 310mm; 150mm x 350mm; 150mm x 380mm; 150mm x 400mm; 150mm x 420mm; 150mm x 440mm; 150mm x 460mm; 150mm x	non sterile	5900516AAEXXXSB



	520mm; 150mm x 540mm; 160mm x 195mm; 160mm x 200mm; 160mm x 220mm; 160mm x 250mm; 160mm x 270mm; 160mm x 300mm; 160mm x 310mm; 160mm x 340mm; 160mm x 390mm; 160mm x 600mm; 200mm x 250mm; 210mm x 270mm; 210mm x 280mm; 210mm x 300mm; 210mm x 310mm; 210mm x 350mm; 210mm x 390mm; 210mm x 400mm; 210mm x 420mm; 210mm x 440mm; 210mm x 490mm; 210mm x 580mm; 250mm x 320mm; 250mm x 360mm; 250mm x 380mm; 250mm x 390mm; 250mm x 400mm; 250mm x 450mm; 250mm x 500mm; 270mm x 350mm; 270mm x 400mm; 270mm x 450mm; 270mm x 520mm; 270mm x 560mm; 300mm x 350mm; 300mm x 420mm; 300mm x 500mm; 300mm x 540mm; 300mm x 570mm; 300mm x 600mm; 320mm x 370mm; 320mm x 400mm; 320mm x 450mm; 320mm x 500mm; 320mm x 550mm; 320mm x 600mm; 350mm x 600mm; 420mm x 500mm; 420mm x 600mm; 420mm x 610mm; 490mm x 650mm		
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**Risk class and classification rule:** I/1

**Product application :** Products are used as the packaging for medical devices during sterilisation process.

**UMDNS code:** 13735

**Applied standards:** PN-EN ISO 13485:2016; PN-EN ISO 62366-1:2015; PN-EN ISO 14971:2020  
PN-EN ISO 15223-1:2017; PN EN ISO 11607-1:2020; PN EN ISO 11607-2:2020  
PN EN ISO 11140-1:2009; PN EN ISO 1041+A1:2013

We declare, under our sole responsibility, that the medical devices described in the declaration bearing the CE marking comply with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) as amended. The declaration has been drawn up on the basis of the requirements in Annex IV of this Regulation.



TZMO SA has a certified quality management system, in accordance with the requirements of the standards: ISO 9001:2015, certificate number PL008673/P (issued by Bureau Veritas Polska Sp. z o.o.) and ISO 13485:2016, certificate number 283504-2019-AQ-POL-FINAS (issued by DNV GL Business Assurance Finland Oy Ab).

Toruń, 20.05.2021

***Tomasz Przybylski***

Deputy Director for Production and Innovation,  
TZMO SA

acting as representative of Toruńskie Zakłady  
Materiałów Opatrunkowych S.A.

/qualified electronic signature/

***Rafał Budzyński***

Plenipotentiary of the President of the Management Board for  
Production and Innovation, TZMO SA


acting as representative of Toruńskie Zakłady Materiałów  
Opatrunkowych S.A.

/qualified electronic signature/

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